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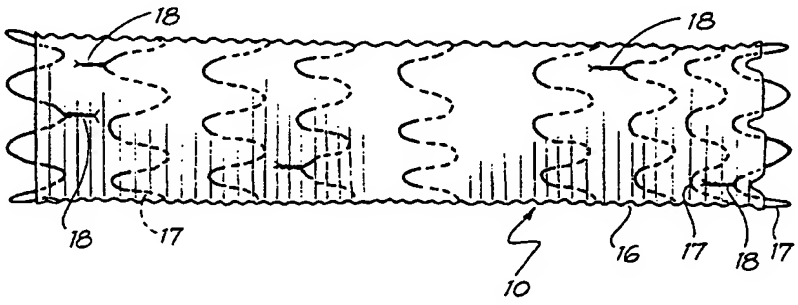

(57) Abstract

An intraluminal graft (10) includes a tubular graft body (11) formed of a film or fabric which is reinforced along its length by a plurality of separate spaced apart maleable wires (17). Each of the wires (17) has a generally closed sinusoidal or zig-zag shape. A wire (17) located adjacent to one end of the graft body (11) has alternate crests or apices that project beyond that end of the graft body (11). The graft (10) may be inserted intraluminally into the body of a patient in a collapsed condition within a catheter. Once positioned to bridge across an aneurysm within the patient's arterial system the graft (10) may be expanded radially by a balloon to bridge the aneurysm and occlude the aneurysmal sack.

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INTRALUMINAL GRAFT

FIELD OF THE INVENTION

The present invention relates to an intraluminal graft for use in treatment of aneurysms or occlusive diseases.

BACKGROUND ART

It is known to use stents and intraluminal grafts of various designs for the treatment of aneurysms such as aortal aneurysms and for the treatment of occlusive diseases such as the occlusion of blood vessels or like ducts such as the bile duct and the ureter (which are all hereinafter called "vessels"). It is known to form such an intraluminal graft of a sleeve in which is disposed a plurality of self expanding wire stents (see Balko A. et al., "Transfemoral Placement of Intraluminal Polyurethane Prosthesis for Abdominal Aortic Aneurysms", Journal of Surgical Research 40, 305-309 (1986); Mirich D. et al, "Percutaneously Placed Endovascular Grafts for Aortic Aneurysms: Feasibility Study" Radiology, Vol. 170, No. 3, part 2, 1033-1037 (1989)). Such intraluminal grafts are inserted through the femoral artery into the aorta in a catheter. Upon the release of the graft from the catheter it expands to the size of the aorta above and below the aneurysms and bridges the aneurysms.

There are a number of problems associated with such known grafts. These include the problem of twisting or kinking of the graft when it has to extend along a non-linear path which, twisting or kinking can lead to occlusion of the lumen of the graft; lack of precise control of the expansion of the graft in the lumen; avoidance of inadvertent separation of a supporting stent and the covering sleeve; and maintaining the graft against longitudinal movement along the lumen in which it is placed. The present invention is directed to an alternative form of intraluminal graft which provides an

alternative to the known grafts.

DISCLOSURE OF THE INVENTION

In a first aspect the present invention consists in an intraluminal graft comprising a tubular graft body which is circumferentially reinforced along its length by a plurality of separate, spaced-apart, maleable wires, each of which has a generally closed sinusoidal or zig-zag shape, one of the wires being located adjacent to one end of the graft body such that alternate crests or apices of the wire projects beyond at least part of that end.

In another aspect the invention relates to a method for positioning an intraluminal graft as defined above comprising introducing a catheter into a vein, artery or other vessel in the body, causing an intraluminal graft as defined above to be carried through the catheter on an inflatable balloon until the graft extends into the vessel from the proximal end of the catheter, inflating the balloon to cause the alternate crests or apices of the one wire to be urged into contact with the wall of the vessel, deflating the balloon and withdrawing the balloon and the catheter from the vessel.

In preferred embodiments of the invention each end of the graft will be provided with a wire which has alternate crests or apices extending beyond the adjacent end of the graft body. While the graft will normally have wires at each end of the graft with their crests extending beyond the graft body it may be necessary or desirable for a surgeon to shorten a graft and this may be achieved by cutting off part of the graft body. In this case the graft will have extending crests at only one end.

The projection of alternate crests or apices of the end wire or wires beyond at least part of the end or ends of the graft body is an important feature of this invention. As the graft is expanded by a balloon the expansion of the wires, and of the balloon, will be

limited by the diameter of the tubular graft body except in the region of the alternate crests or apices of the end wire or wires. The balloon will be able to expand these crests slightly more than the remainder of the wire so that they bell outwardly away from the adjacent end of the graft body. The crests are forced into contact with the wall of the vessel and thereby become at least partly embedded into the vessel wall. This belling out of the crests of the wires at one or both ends of the graft body into contact with the inside surface of the vessel wall and then being at least partly embedded in the wall will assist in resisting any tendency for the graft to move longitudinally within the vessel after insertion. The wire crests may extend across the lumen of a vessel opening into the vessel in which the graft is being placed without occluding that lumen. This allows the intraluminal graft to be used in situations in which the aneurysm to be bridged commences closely adjacent divergent blood vessels. In most cases there will be crests of wire actually projecting totally beyond the end of the graft materials. It would, however, be possible to have flaps of graft material protruding up the outside of each crest even though intermediate the crests the end of the graft stops well short of the crests. In this latter arrangement the crests are still free to bell outwardly as has been described above even though the crests do not extend absolutely beyond the end of the graft.

It is preferred that the one wire has a greater amplitude than at least the next adjacent one or two wires. This allows the wires at the end of the graft to be positioned more closely together than would be the case if they were all of the same amplitude. It is desirable to space the wires adjacent the end of the graft that will be placed "upstream" in the patient as close together as is possible as the neck of the aneurysm with which the

graft is engaged can be quite short. Close spacing of the wires maximises the number of wires reinforcing that part of the graft in contact with the neck of the aneurysm. The spacing of the rest of the wires is desirably greater than those adjacent the one end of the graft as this avoids unnecessarily reducing the flexibility of the graft.

The wavelength of the wires in the graft is preferably substantially the same when compressed however when expanded the end wires will have a shorter wavelength than the intermediate wires as the intermediate wires will not bear against the arterial wall and may therefore be more fully expanded.

It is preferred that the edge of the one end of the graft is scooped out or scalloped between each projecting crest of the one wire. This reduces the possibility that a piece of the graft between those crests could project into the arterial lumen and partially occlude it or direct blood around the outside of the graft.

The tubular graft body is preferably formed of a thin biocompatible material such as Dacron or PTFE. The tube material is preferably crimped along its length to increase its flexibility, however, uncrimped material may be used in suitable circumstances. In preferred embodiments of the invention the graft body may be formed from a material having a limited amount of diametric elasticity to ensure that it can be expanded into contact with the vessel wall. The length and diameter of the graft body will be determined by the individual circumstances of the application to which the intraluminal graft is to be put. Typically, the vessel will be assessed by X-ray or other similar examination and a suitably dimensioned graft selected for that application.

The wires are preferably formed of stainless steel or another metal or a plastic which is maleable and is biocompatible. Each wire is preferably woven into the

fabric of the graft body to integrate the body and the reinforcing wires. This prevents any possibility of the wire reinforcement separating from the graft body during introduction of the graft or throughout its life. If the graft body is of a woven material the wires may be interwoven with the graft body during its production or alternatively they may be interwoven with the graft body after its manufacture. If the graft body is not woven but is knitted or of an impervious sheet material then the wires may be threaded through suitable holes formed in the graft body. The interweaving of the wires with the graft body has been found to be particularly desirable as it prevents separation of the wires from the graft body which could have serious adverse consequences. It has also been found that this technique is very good for causing the graft to expand effectively with the wires.

In alternative embodiments the wires may be held in place by sutures or adhesives or may be sandwiched between layers of a multi-layered tubular graft body. In all of the foregoing arrangements the wires are preferably disposed substantially within the graft body. It is, however, within the ambit of the invention that the wires may be connected to, and be disposed on, the outside surface of the graft body.

The intraluminal grafts according to this invention may be used to treat aneurysms or occlusive disease. In addition to treating aortic aneurysms they are particularly suitable for treating aneurysms of the femoral artery, the popliteal artery, the thoracic segment of the aorta, visceral arteries such as the renal and mesenteric arteries, the iliac artery and the sub-clavian artery. The presence of the metal wires in the intraluminal grafts according to this invention assists in placing the graft as the wires are X-ray detectable. As the wires are arrayed along the length of the graft the

complete position of the graft in the body can be continuously monitored.

The grafts according to this invention are typically substantially of constant diameter along their length ie, they are substantially cylindrical. It is possible, however, for the grafts to be frusto-conical in shape with a diameter that increases, or decreases, along the length of the graft.

The ends of the wires are joined together to form a tail which is preferably on the outside of the graft body and is positioned to lie along its radially outer surface. The ends may be joined by welding, by being twisted together or in any other suitable manner. The ends of the wires may inadvertently perforate the vessel in which the graft is placed, however, any such perforation will be occluded by the graft body thus ensuring that such a perforation will not adversely affect the patient. The ends of adjacent wires are preferably spaced apart radially about the graft body so as not to affect its flexibility and to avoid a line of ends engaging the wall of the vessel. The ends of adjacent wires preferably project in opposite directions along the vessel body. When the intraluminal graft is inserted into a vessel those wire ends which engage the inside surface of the vessel wall will assist in preventing the graft from inadvertent movement along the vessel. Causing the ends of alternate wires to project in opposite longitudinal directions along the graft body will assist in preventing longitudinal movement of the graft along the vessel in either direction.

In some circumstances it is desirable to insert two or more overlapped intraluminal grafts according to the present invention. In this case the first or upstream graft preferably has at its downstream end a "skirt" without reinforcing wires. This skirt is typically 10 to

15 mm in length. The second or downstream graft is inserted into the downstream end of the first graft and is expanded to engage with it. There is preferably an overlap of at least 10 mm however the degree of overlap is often adjusted so that the downstream end of the second graft is correctly placed in the downstream neck of the aneurysm being treated. This can lead to a greater overlap than is the minimum required but is a useful technique to ensure that the overall length of the graft is correct.

It is sometimes the case that the aneurysm extends up to or slightly beyond an arterial bifurcation. In such a case it is possible to place a graft according to the present invention which has a bifurcation at its downstream end, a so-called "trouser graft", wholly within the primary artery. A supplemental graft may then be introduced through each of the subsidiary arteries and overlapped with the respective lumenae of the bifurcated part of the primary graft. In the case of an aneurysm in the aorta, for instance, that extended into each of the iliac arteries the primary graft of the "trouser" type would be placed in the aorta through one of the iliac arteries. Supplemental grafts which dock with the bifurcated end of the primary graft would then be inserted through each of the iliac arteries.

In those cases where one graft according to this invention is to be inserted into the downstream end of another such graft it may be desirable to provide means to stop the "skirt" on the downstream end of the other graft from being distorted by the insertion of the one graft. This may conveniently be done in one or other of two ways. The skirt may be provided with a small number of linear reinforcement wires extending longitudinally of the graft. In this case, the wires are spaced about the circumference of the skirt. Alternatively, the skirt may

be provided with at least one resilient annular reinforcement wire. The resilient reinforcement wire will spring into an expanded condition upon being released from the catheter through which it is introduced into the body. This latter arrangement is particularly suitable in the case of "trouser grafts" wherein one leg of the graft will have a skirt which cannot be expanded by a balloon catheter.

BRIEF DESCRIPTION OF DRAWINGS

Hereinafter given by way of example is a preferred embodiment of the present invention described with reference to the accompanying drawings, in which:-

Fig. 1 is a diagrammatic partially cut-away ventral view of a patient with an aortic aneurysm which has been bridged by an intraluminal graft according to the present invention;

Fig. 2 is a side elevational view of the intraluminal graft of Fig. 1;

Fig. 3 is a longitudinal sectional view through the intraluminal graft of Fig. 2;

Fig. 4 is a detailed longitudinal sectional view through the intraluminal graft of Fig. 2 as it is being expanded into contact with the aorta of a patient during placement;

Fig. 5 is a detailed longitudinal sectional wire through the intraluminal graft of Fig. 2 after it has been inserted into the aorta of a patient;

Fig. 6 is a detailed elevational view of one end of the intraluminal graft of Fig. 2; and

Fig. 7 is a detailed perspective view of the one end of the intraluminal graft of Fig. 6 showing how the alternate crests of the end wire of the graft are pushed radially outwardly during insertion of the graft.

BEST MODE OF CARRYING OUT THE INVENTION

The intraluminal graft 10 is adapted for insertion

transfemorally into a patient to achieve bridging and occlusion of the aneurysm present in the aorta. As is seen in Fig. 1 the aorta 11 is connected to the left and right femoral arteries 12 and 13. The aortic aneurysm is located between the renal arteries 14 and 15 and the junctions of the femoral arteries 12 and 13 with the aorta 11. The graft 10 is, as will be described subsequently in more detail, inserted inside a catheter introduced into one of the femoral arteries 12 or 13 in a leg of the patient. Once the catheter is located appropriately with its proximal end in the aorta 11 the graft 10 is ejected from the catheter and expanded so that each end is in intimate contact around its full periphery with the aorta 11. The graft 10 then bridges the aneurysm and isolates any thrombosis or gelatinuous material associated with the aneurysm outside the graft 10 to reduce the risk of embolisation.

The intraluminal graft 10 comprises a crimped tube 16 of woven Dacron. The tube is reinforced along its length by a number of separate and spaced apart stainless-steel wires 17 (each of which has a generally closed sinusoidal shape). The wires 17 are preferably as thin as possible and are typically 0.3 to 0.4 mm in diameter. The wires 17 are maleable and may be bent into any desired shape, ie they are not resilient to any substantial extent so that they have to be physically expanded into contact with the aorta rather than expanding by virtue of their own resilience. The wires 17 are each woven into the fabric of the tube 16 such that alternate crests of each wire 17 are outside the tube 16 with the remainder of that wire 17 inside the tube (except in the case of the endmost wires as will be hereinafter described). The ends of each wire 17 are located outside the tube 16 and are twisted together to form a tail 18. The tails 18 of alternate wires 17 are bent to extend in opposite longitudinal

directions along the outside surface of the tube 16.

The endmost ones of the wires 17 overhang the respective ends of the tube 17 so that alternate crests of those wires extend longitudinally beyond the end of the tube 16. The endmost wire 17 preferably has an amplitude of about 6 mm and a wavelength such that between six and eight crests are spaced around the circumference of a 22 mm diameter graft. The next two adjacent wires 18 preferably are spaced as close as possible to the wire 17 and respectively have amplitudes of 4 mm and 5 mm. These wires will typically have the same wavelength initially as the wire 17. Thereafter throughout the graft 10 the wires 18 are spaced at 15 mm intervals, have an amplitude of 6 mm, and have substantially the same initial wavelength as the wire 17.

In use the graft 10 is radially compressed about an inflation balloon 19 (see Fig. 4) and the assembly is inserted into the end of a sheath catheter 21. The sheath catheter 21 is inserted in a known manner through the femoral artery into the aorta 11 until the proximal end of the catheter 21 is beyond the proximal end of the aneurysm. The balloon 19 and the collapsed graft 10 disposed on it, are held stationary and the catheter withdrawn until the graft 10 is fully exposed and spans the aneurysm. The balloon is then inflated to expand the graft 10. The diameter of the tube 16 determines the maximum expansions of the majority of the graft 10 and this diameter has been selected in advance by X-ray examination, or the like, to be substantially equal or only very slightly larger than, the diameter of the undistended aorta 11. The balloon is, however, able to expand the alternating crests of the end wires 17 so that they are pushed firmly into contact with the wall of the aorta. These radially outwardly displaced crests serve to more effectively restrain the graft 10 against longitudinal movement relative to the aorta.

CLAIMS:-

1. An intraluminal graft comprising a tubular graft body which is circumferentially reinforced along its length by a plurality of separate, spaced-apart, maleable wires, each of which has a generally closed sinusoidal or zig-zag shape, one of the wires being located adjacent to one end of the graft body such that alternate crests or apices of the wire projects beyond at least part of that end.

2. An intraluminal graft as claimed in claim 1 in which each end of the graft body is provided with a wire which has alternate crests or apices extending beyond the adjacent end of the graft body.

3. An intraluminal graft as claimed in claim 1 in which the one wire has a greater amplitude than the next adjacent wire, and preferably the next two adjacent wires.

4. An intraluminal graft as claimed in claim 1 in which wires adjacent the one end of the graft body are more closely spaced than wires intermediate the ends of the graft body.

5. An intraluminal graft as claimed in claim 1 in which the wavelength of the wires is substantially constant along the length of the graft body.

6. An intraluminal graft as claimed in claim 1 in which the one wire has a greater amplitude and a smaller wavelength than at least a majority of the other wires in the graft.

7. An intraluminal graft as claimed in claim 1 in which the edge of the one end of the graft is scooped out or scalloped between each projecting crest or apex of the one wire.

8. An intraluminal graft as claimed in claim 1 in which wires are interwoven with the graft body.

9. An intraluminar graft as claimed in claim 8 in which the ends of each wire are twisted together on the outside of the graft body.

10. An intraluminar graft as claimed in claim 1 in which the alternate crests or apices extend completely beyond the end of the graft body.

11. A method for positioning an intraluminal graft, comprising introducing a catheter into a vein, artery or other vessel in the body, causing an intraluminal graft as claimed in any one of claims 1 to 10 to be carried through the catheter on an inflatable balloon until the graft extends into the vessel from the proximal end of the catheter, inflating the balloon to cause the alternate crests or apices of the one wire to be urged into contact with the wall of the vessel, deflating the balloon and withdrawing the balloon and the catheter from the vessel.

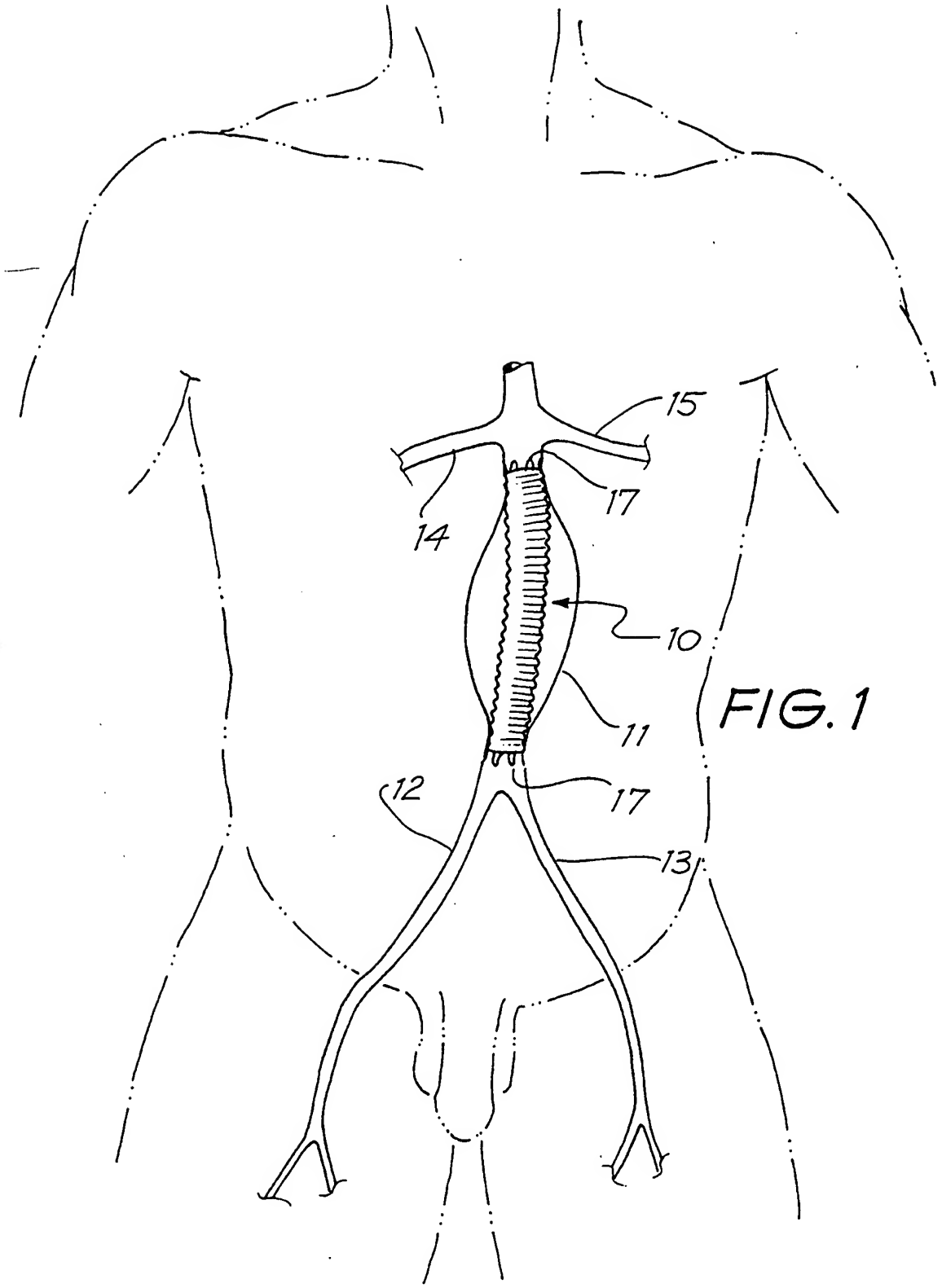


FIG. 1

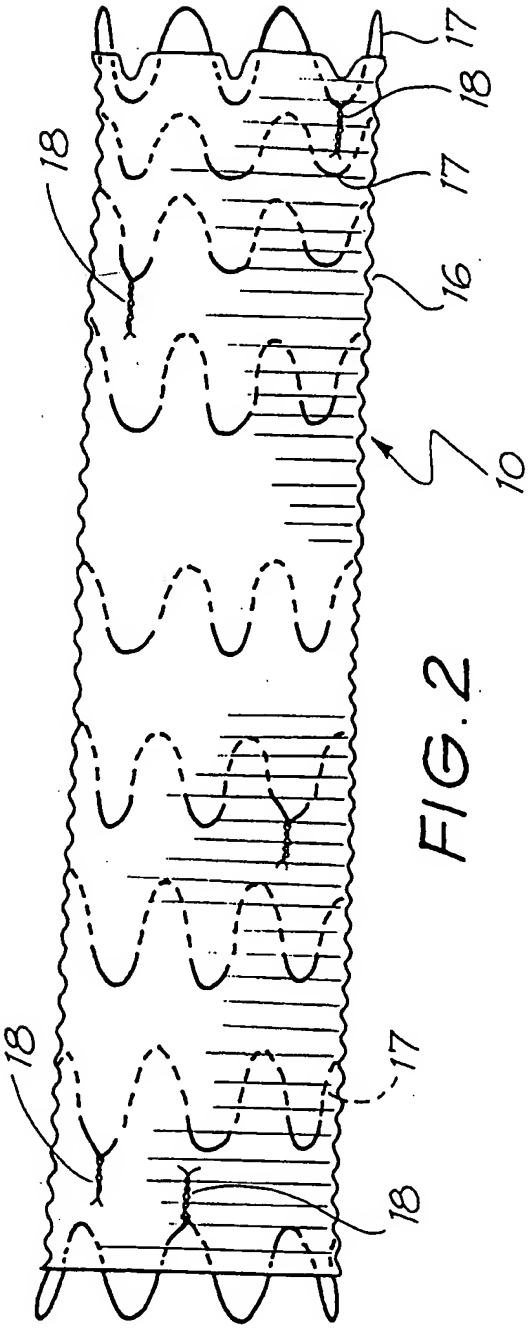


FIG. 2

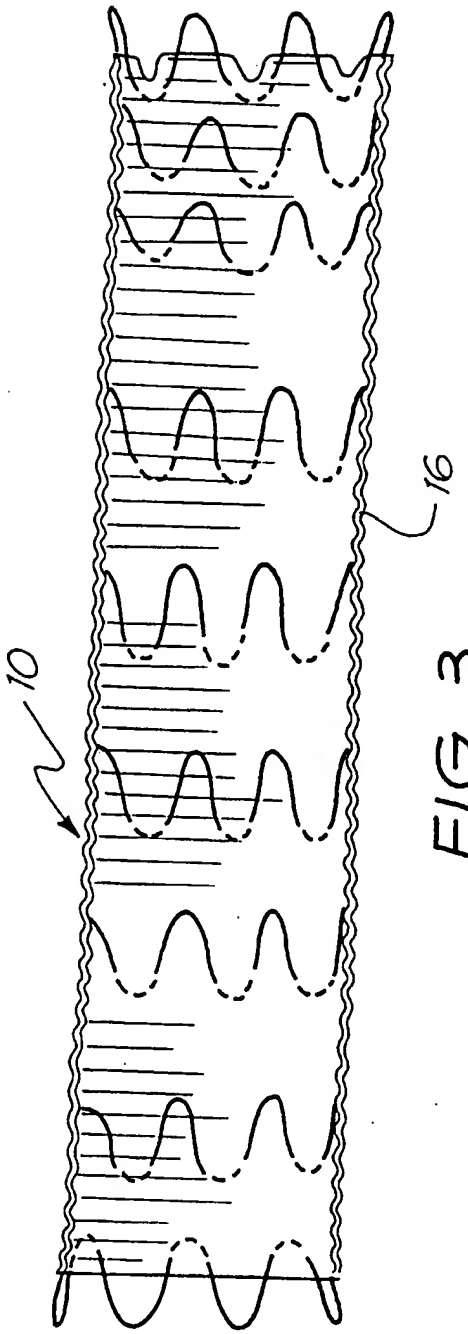


FIG. 3

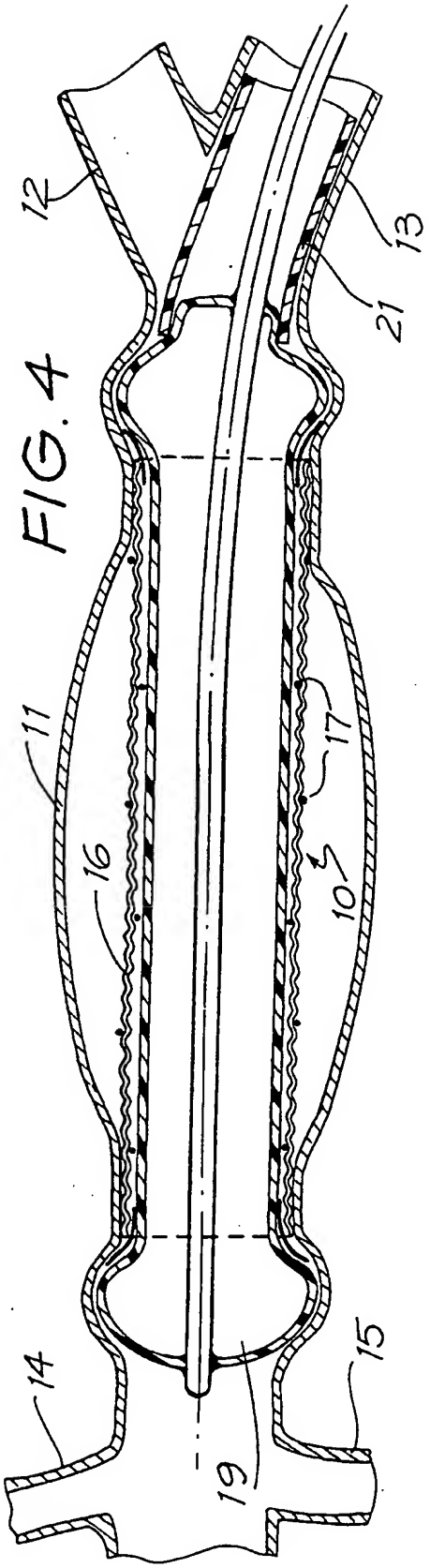


FIG. 4

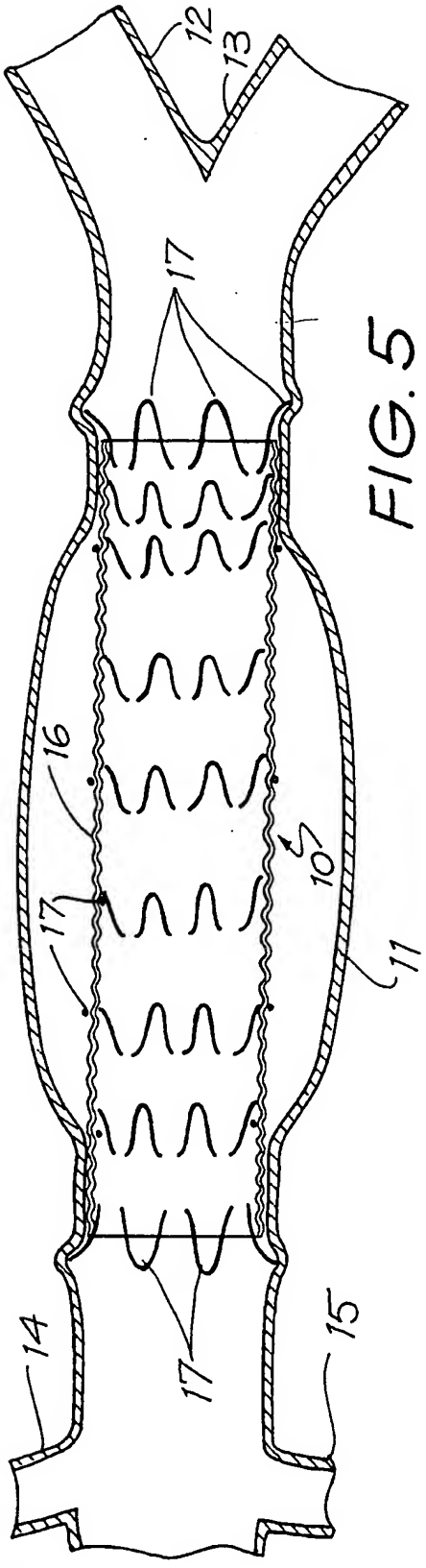


FIG. 5

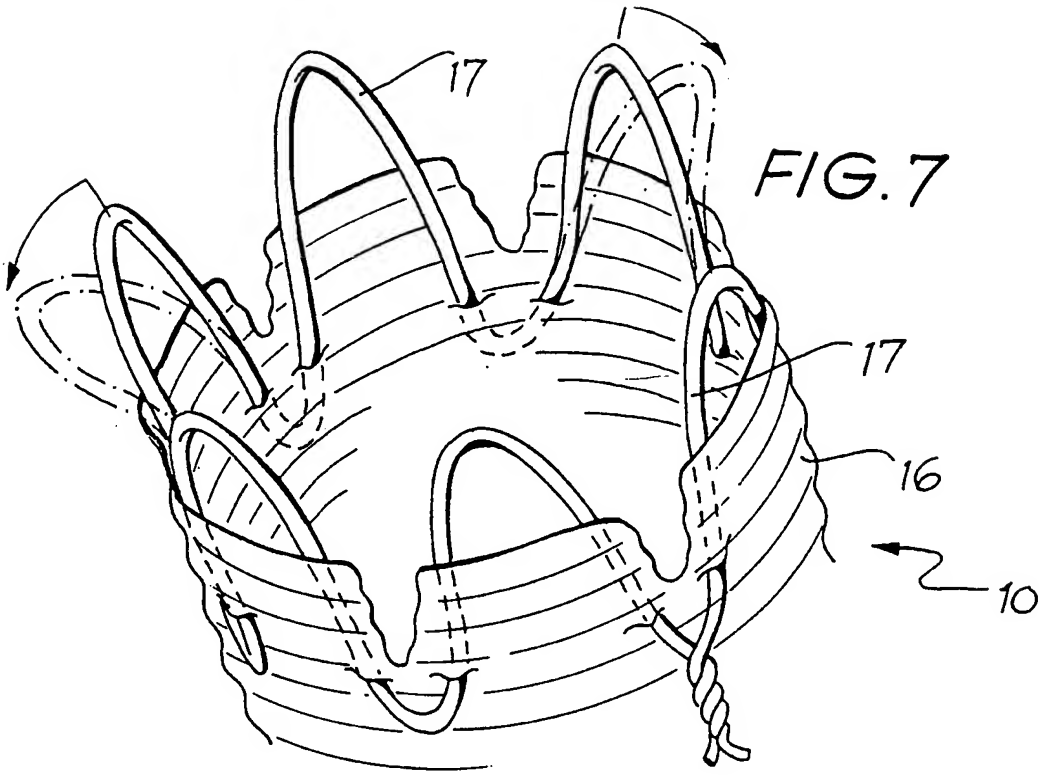
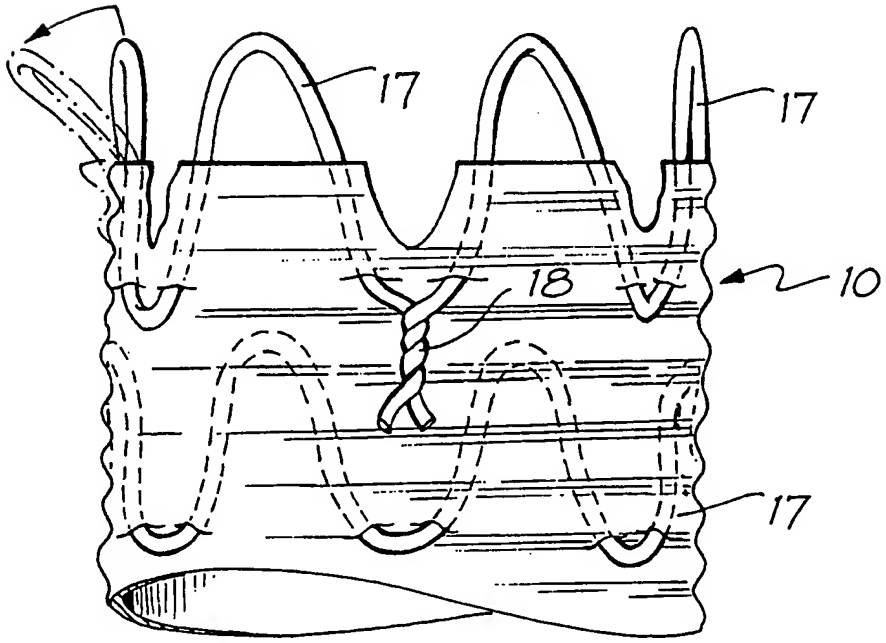


FIG. 7

FIG. 6



INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU 94/00586

A. CLASSIFICATION OF SUBJECT MATTER
Int. Cl.[6] A61F 2/06

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B. FIELDS SEARCHED

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C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to Claim No.
X	Patent Abstracts of Japan, C1019, page 45, JP,A, 4-253856 (TERUMO CORP) 9 September 1992 (09.09.92) Abstract and Figure	1, 5, 7-10, 11
X	Patent Abstracts of Japan, C1089, page 54, JP,A, 5-76603 (OLYMPUS OPTICAL CO LTD) 30 March 1993 (30.03.93) Abstract and Figure	1, 5, 7-10, 11
A	WO,A, 83/03752 (WALLSTEN) 10 November 1983 (10.10.83)	

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Date of the actual completion of the international search
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Date of mailing of the international search report
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INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU 94/00586

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	**Citation of document, with indication, where appropriate of the relevant passages**	**Relevant to Claim No.**
A	WO,A, 89/01320 (E I DU PONT DE NEMOURS AND COMPANY) 23 February 1989 (23.02.89)	
A	WO,A, 92/06734 (SONG) 30 April 1992 (30.04.92)	
A	US,A, 5163958 (PINCHUK) 17 November 1992 (17.11.92)	
A	EP,A, 540290 (ADVANCED CARDIOVASCULAR SYSTEMS, INC) 5 May 1993 (05.05.93)	

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Information on patent family membe.

International application No.
PCT/AU 94/00586

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

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WO	8303752	AU	15186/83	BE	896616	BR	8307541
		CA	1239755	CH	662051	DE	3342798
		DK	159368	FR	2525896	GB	2135585
		IT	1169405	JP	4047575	NL	8320142
		SE	445884	US	4655771	US	4954126
JP	076603						
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END OF ANNEX